DEC 11 2001

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5 Network and Central '01

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:
Mr. Joel Kent

DATE:
September 25, 2001

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5 Network and Central '01

COMMON NAME:

Clinical network and central station

CLASSIFICATION NAME:

The following Class III classification appears applicable:

System, network and communication, physiological monitors	870.2910

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5 Network and Central '01 is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Network and Central and Information Center (510(k) number: K000647).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda S/5 Network (also referred as D-O Network in the related documentation) is a system, which consists of networked devices (which have separate 510k clearance) and the actual networking hardware. The networked devices are Datex-Ohmeda products containing a network adapter for physical access to the D-O Network as well as software modules supporting network access.

Examples of currently available networked devices are:
1. Datex-Ohmeda S/5 Anesthesia Monitor
2. Datex-Ohmeda S/5 Compact Anesthesia Monitor
3. Datex-Ohmeda S/5 Critical Care Monitor
4. Datex-Ohmeda S/5 Compact Critical Care Monitor
5. Datex-Ohmeda S/5 Light Monitor
6. Datex-Ohmeda S/5 Cardiocap 5 Monitor
7. Datex-Ohmeda S/5 Network and Central, included in this 510(k)
8. Datex-Ohmeda S/5 Telemetry System

The DeioRecorder for Anesthesia (formerly named as Datex-Ohmeda AS/3 Record Keeper.) is also related to the D-O Network as an application using the services provided by the D-O Network.
No changes must be made to the Datex-Ohmeda S/5 Network and Central itself due to a new type of networked device.

The Datex-Ohmeda S/5 Central (also referred to as D-O Central in the related documentation) is the primary maintainer of communication between other networked devices and is, thus, an essential part of the network. The structure and functionality of the revised network corresponds to the structure and functionality of the substantially equivalent predicate device Datex-Ohmeda Network and Central (510(k) number: K000647).

The Datex-Ohmeda Network will be used for real-time communication between devices, for record keeping and for data management in a hospital. Practical examples of currently available features are:
- Transmission and display of measured values and alarms in the Datex-Ohmeda S/5 Central screen (central monitoring) and on the screen of another networked monitor (monitor-to-monitor communication).
- Anesthesia record keeping.
- Storing and transferring of trend and record keeping data in the network. When the patient is moved from one monitor to another, the data can be transferred with the patient. This feature includes also transferring data from/to an external system (HIS, laboratory, etc.) to/from Datex-Ohmeda S/5 Network.
- Printing of anesthesia records, ICU reports, trend printouts, spirometry loop printouts, waveform snapshot printouts, etc.

The actual networking hardware consists of cabling, patch panels, racks, connectors, repeaters, etc. The networking hardware is similar to the networking hardware of the substantially equivalent predicate device Datex-Ohmeda Network and Central (510(k) number: K000647).

The Datex-Ohmeda S/5 ViewStation is a D-O Central version that can show real-time curves and numeric information from any monitor residing in the Datex-Ohmeda Network. It also allows printing to laser printer or recording to a strip-chart recorder. The Datex-Ohmeda S/5 ViewStation does not store patient data, or provide any other network services

than display and printing services. The ViewStation uses the same hardware and a subset of the software used by the main Central.

The Datex-Ohmeda S/5 Telemetry System Network is a computer-based system for monitoring patients using telemetry. It consists of a PC based Central Station including receivers, antenna network, and up to 16 telemetry transmitters per station. The central station supports arrhythmia monitoring, and measuring and trending of ST changes. An S/5 TeleNet Package has been developed to enable connection of Telemetry central to D-O Network. The package enables transfer of ECG waveforms, ECG related parameters and arrhythmia information to the D-O Network. Also bed-to-bed services from telemetry sessions to bedside monitors are made available.

The new version of Datex-Ohmeda S/5 Network and Central adds the following features:
- Commercial hardware: The display driver is a commercial board instead of D-O proprietary boards. The proprietary keyboard is not used anymore, instead there is a commercial keyboard with dedicated "EasyAccess" keys
- User Interface is now mouse controlled in addition to keyboard controlled
- Numerical and graphical trends have been added
- Alarm management functionality has been extended: remotely silencing of bedside alarms and changing alarm limits from Datex-Ohmeda S/5 Central or ViewStation have been added
- Monitor disconnection warning on Central has been added
- Possibility to start a network recorder from a bedside monitor has been added
- TeleNet Package to enable connection of Datex-Ohmeda S/5 Telemetry System to D-O Network

INTENDED USE as required by 807.92(a)(5)

The Datex-Ohmeda S/5 Network and Central is intended to be used with Datex-Ohmeda devices for displaying, storing, printing and otherwise processing information received from other networked devices.

The Datex-Ohmeda S/5TM Network and Central transfers information between networked Datex-Ohmeda devices in the Datex-Ohmeda monitor network. It also allows information transfer between several Centrals. Within one Datex-Ohmeda monitor network it allows a networked device to display, store, print and otherwise process information received from other networked devices.

The Datex-Ohmeda S/5TM Central maintains the network connections between the Datex-Ohmeda bedside monitors and other networked devices in Datex-Ohmeda monitor network. Furthermore, it coordinates the transfer of information between devices in the Datex-Ohmeda S/5TM Network as well as between the Datex-Ohmeda Network and Hospital Information Systems (HIS).

The Datex-Ohmeda S/5TM Central can be used for remote monitor management, storing, printing, viewing or otherwise processing of information from several bedside monitors or other networked devices.

The Datex-Ohmeda S/5TM ViewStation can be used for remote monitor management, printing, viewing or otherwise processing of information from several bedside monitors or other networked devices.

The Datex-Ohmeda S/5TM Network will be used for patients in the hospital and it is meant for continuous use.

The device is for use by qualified personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5 Network and Central is substantially equivalent in safety and effectiveness to the Datex-Ohmeda S/5 Network and Central and Information Center (510(k) number: K000647).

Similarities:

The indications for use is the same as in predicate except that "remote monitor management" has been expressed in the statement.

The structure and functionality of the Datex-Ohmeda S/5 Network and Central '01 closely corresponds to the structure and functionality of the Datex-Ohmeda Network and Central '99 (predicate). The basic architecture of Datex- Ohmeda S/5 Network and Central '01 is the same as that of Datex-Ohmeda Network and Central '99 (predicate).

The user interface uses the same basic functionality: Single patient view and multiple patient views are similar to the predicate. Alarm indications are similar.

The ability to have audible alarm indications only on the Central is similar to the predicate.

Differences:

The hardware platform now uses commercial graphics controller and normal PC keyboard instead of D-O proprietary versions.

The user interface can now also be controlled with a mouse. The Central uses a PC keyboard that has labeled special "Easy Access" keys. The earlier keyboard was proprietary with special keys.

Remote monitor management adds the option to silence bedside monitor alarms from the Central and to adjust monitor alarm limits. These functions are by default disabled. They can be activated by the system administrator and activation is password protected.

Numerical and graphical trend display has been added to the Central.

Monitor disconnection warning has been added since Central may in some cases be used for monitoring alarms.

Possibility to start a network recorder from monitor has been added to support work methods of e.g. some intensive care units.

A SW package to enable S/5 Telemetry system integration to the D-O Network has been developed. It uses similar connection to the network as the Central.

Summary:

In summary, the new Datex-Ohmeda S/5 Network and Central, described in this submission is substantially equivalent to the predicate (K000647) device.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5 Network and Central '01 complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- EN60950: 1995 (IEC950 2nd edition) - Safety of information technology equipment, including electrical business equipment
- EN 55022: 1994 (IEC-CISPR 22) – Information technology equipment - Radio disturbance characteristics. Limits and methods of measurement
- EN 55082-1: 1991 (IEC 801-2, IEC 801-3, IEC 801-4) – Electromagnetic compatibility - Generic immunity standard
- EN 1441, Medical devices - Risk analysis
- EN 475, Medical devices - Electrically-generated alarm signals
- ISO 9703-1, ISO 9703-2, Anesthesia and respiratory care alarm signals
- IEC 60601-1-4
- CAN/CSA-C22.2 No 950: Information Technology Equipment Including Electrical Business Equipment
- UL1950: Information Technology Equipment Including Electrical Business Equipment
- ISO/IEC 8802-3 (ANSI/IEEE 802.3), EIA/TIA-568, EIA/TIA-TSB40, international network cabling standards

Conclusion:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5 Network and Central as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2001

Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
Datex Ohmeda
86 Pilgrim Road
Needham, MA 02492

Re: K013246
Trade Name: Datex-Ohmeda S/5 Network and Central '01
Regulation Number: 21 CFR 870.2300
Regulation Name: Network and Communication Physiological System
Regulatory Class: Class II (two)
Product Code: MSX
Dated: September 26, 2001
Received: September 28, 2001

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

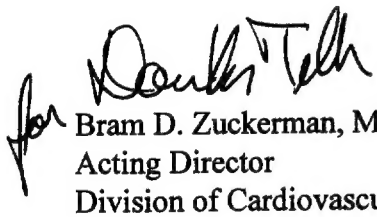
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013246

Device Name: Datex-Ohmeda S/5 Network and Central '01

Indications For Use:

The Datex-Ohmeda S/5™ Network and Central transfers information between networked Datex-Ohmeda devices in the Datex-Ohmeda monitor network. It also allows information transfer between several Centrals. Within one Datex-Ohmeda monitor network it allows a networked device to display, store, print and otherwise process information received from other networked devices.

The Datex-Ohmeda S/5™ Central maintains the network connections between the Datex-Ohmeda bedside monitors and other networked devices in Datex-Ohmeda monitor network. Furthermore, it coordinates the transfer of information between devices in the Datex-Ohmeda S/5™ Network as well as between the Datex-Ohmeda Network and Hospital Information Systems (HIS).

The Datex-Ohmeda S/5™ Central can be used for remote monitor management, storing, printing, viewing or otherwise processing of information from several bedside monitors or other networked devices.

The Datex-Ohmeda S/5™ ViewStation can be used for remote monitor management, printing, viewing or otherwise processing of information from several bedside monitors or other networked devices.

The Datex-Ohmeda S/5™ Network will be used for patients in the hospital and it is meant for continuous use.

The device is for use by qualified personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013246